

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I.      Summary of the Interview**

Applicant thanks the Examiner for the courtesy of the interview of October 11, 2011 between Examiner Gussow and Applicant's representatives Simon Elliott and Paul Wiegel. That interview is accurately reflected in the Interview Summary mailed October 14, 2011, and in the foregoing claim amendments and the following comments in this response.

**II.     Amendments to the Specification**

The specification is amended at pages 46 and 47 to insert the required sequence identifiers. No new matter is added.

**III.    Status of the Claims**

Claims 1-84, 90, 97, 106, and 109-141 are cancelled. Claims 1-84, 90, 97, 106, and 114 were previously cancelled, and claims 118-125 and 128-139 were previously withdrawn.

Claims 85-89 and 93-96 are amended to remove recitation of "functional fragment thereof." Claims 100-105 are amended to replace "functional fragment thereof" with "antibody fragment containing an antigen-binding region," as found in *e.g.* the abstract and ¶ 0063 of the published specification. Claims 100 and 101 are also simplified.

Claims 142-148 have been added, and recite specific embodiments within the scope of claim 100 and 101. Support for these claims can be found, for example, at Figure 7 and ¶¶ 0136-0138 of the published specification.

The foregoing amendments to the claims do not impermissibly add new matter, and are made solely to advance prosecution, without disclaimer of subject matter removed by amendment, and without acquiescence to any basis of rejection.

Following entry of the foregoing amendments, pending are independent claims 85, 93 and 100, and dependent claims 86-89, 91-92, 94-96, 98-99, 101-105, 107-108 and 142-148. Favorable consideration of the claims is requested.

**IV. Priority**

In view of the July 27, 2011, Decision on Petition Under 37 C.F.R. § 1.78(a)(6), Applicant believes to have met all requirements for a claim for priority benefit of a prior application.

**V. Information Disclosure Statement and the corrected PTO Form SB08 submitted with this response**

The Information Disclosure Statement filed on September 5, 2008, was returned by the Examiner with lines through six citations on Form PTO/SB/08b. Although not stated by the Examiner, it is believed that these citations were lined through because the citations failed to comply with 37 C.F.R. § 1.98, notably because the date of publication was not provided. Applicant submits herewith a Corrected PTO Form SB08 listing four of the six unconsidered references, along with the publication date of each reference. Copies of the four references listed on the SB08 submitted herewith are found in the Image File Wrapper as of September 5, 2008.

Only four of the six references are cited on the new SB08. “Jackson D.C. et al.” on page 3 of Form PTO/SB/08b is identical to “J. IMMUNOL. 1990, 144:2811,” on page 4, of Form PTO/SB/08b. “PNAS 1980 77:1588,” listed on page 4 of Form PTO/SB/08b, is background art and is not material to the examination of the present claims. Accordingly, only four references remain to be marked as considered.

Entry and consideration are respectfully requested, and an initialed SB08 form is solicited. If any fee is due for the submission of the Corrected PTO Form SB08, the last page of the present document provides authorization to charge such fee.

## **VI. Objections to the Specification**

The objection to the specification was based on the failure to provide unique sequence identifiers (*i.e.*, SEQ ID NOS) to sequences listed on pages 46 and 47 of the specification. Applicant thanks the Examiner for identifying this error, which is believed to be overcome by the foregoing amendment to the specification. Because these sequences were already part of the sequence listing, there is no need to submit a replacement. Withdrawal of the objection is sought.

## **VII. Objections to the Claims**

The cancellation of claims 140 and 141 renders moot their objection

## **VIII. Rejections under 35 U.S.C. § 112, ¶ 2**

Cancellation of claims 126 and 127 renders moot their rejection.

## **IX. Enablement**

Claims 85-89, 91, 92, and 117 are rejected under the enablement clause of 35 U.S.C. § 112, ¶ 1 because there is no Biological Deposit Declaration concerning the cell lines recited in the claims. MPEP § 2404.01 explains that an applicant can show that the biological material is accessible because it is known and readily available to the public.

The cell lines recited in the claims are known and readily available to the public.

Claim 85 states LP-1 (DSMZ: ACC41) and RPMI-8226 (ATCC: CCL-155). Paragraph 0119 of the published specification explains that DSMZ stands for the German Collection of Microorganisms and ATCC stands for the American Type Culture Collection. Both of these are recognized depositories under the Budapest treaty. The numbers that follow, DSMZ: ACC41 and ATCC: CCL-155 are the catalogue numbers. A quick search of the depositories' websites, (<http://www.dsmz.de/catalogues/catalogue-human-and-animal-cell-lines.html>, <http://www.atcc.org> , both of which were accessed 13 October 2011) using the catalog numbers recited in the claims, shows that these cell lines are readily available to the public. In addition, both depositories provide the primary references. The LP-1 cell line is well known from Pegoraro, L., et al. (1989) "The human myeloma cell line LP-1: a versatile model

in which to study early plasma-cell differentiation and c-myc activation, *Blood* 73(4):1020-1027." The RPMI-8226 cell line was first described in Matsuoka,Y., et al. (1967) "Production of free light chains of immunoglobulin by a hematopoietic cell line derived from a patient with multiple myeloma," *Proc.Soc.Exp.Biol Med* 125(4):1246-1250.

Thus, the LP-1 and RPMI-8226 cell lines are published and known, and are deposited at major Budapest-recognized depositories. The claims and specification provide all the information necessary to acquire the cell lines. Accordingly, the cell lines are known and available to the public within the meaning of MPEP § 2404.01, and the person of skill in the art would perceive no barrier to making and using the invention, per 35 U.S.C. 112, ¶ 1. Applicant respectfully requests the Examiner to withdraw the rejection.

**X. Written description.**

Claims 85-89, 91-96, 98-105, 105-113, 115-117, 126, 127, 140 and 141 are rejected under the written description clause of 35 U.S.C. § 112, ¶ 1. Applicant respectfully traverses the rejection as it might have been applied to the pending claims.

The rejection is based on the recitation of "60% sequence identity" "functional fragment" and "competes." These terms have been removed by amendment.

The amended claims comply with the written description requirement.

As shown in Table 2, 4 antibodies have the ADCC functional features of claim 85.

As shown in Table 2, 3 antibodies have the CDC functional features of claim 93.

As shown in Figure 7 and ¶¶ 0136-138, 4 antibodies bind within amino acids 44-206, and therefore support the features of claim 100, and its dependent claims.

For each claim, these are a "sufficient description of a representative number of species by actual reduction to practice" MPEP 2163, citing to *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). The number of species required to demonstrate support for the genus is low because the person of skill in the art is familiar with the functional assay.

Applicant respectfully requests the Examiner to withdraw the rejection.

**XI. Anticipation**

Claims 100, 101, 107, 108 and 117 are rejected under 35 U.S.C. § 102 as allegedly anticipated by Logtenberg (U.S. Patent Application Publication No. 2003/0211553, “Logtenberg”). Applicant respectfully traverses.

Claim 100 recites that the epitope(s) lie in amino acids 44-206, as demonstrated by the epitope mapping shown in Fig. 7 and described in ¶¶ 0136-0138. Dependent claims 101 and 142-148 are even more specific regarding binding to the epitope. Claims 107 and 108 depend from 100, and claim 117 is cancelled.

Logtenberg teaches the UM16 scFv, which is specific for CD38. Logtenberg at ¶ 0053 states “In binding inhibition assays, binding of UM16 to CD38 was almost completely blocked OKT10.” Logtenberg further provides that “The epitope of the OKT10 antibody has been mapped to residues 280-298 at the carboxyl terminus of the 300 residue CD38 molecule.” Therefore, the UM16 antibody fragment of Logtenberg binds to a different epitopes and cannot anticipate. Applicant respectfully requests the Examiner to withdraw the rejection.

**CONCLUSION**

The foregoing amendments agree with those that the Examiner indicated are allowable in the Interview. Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

Examiner Gussow is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Regarding the captioned application, the Commissioner is hereby authorized to credit any overpayment or to charge any additional fees which may be required under 37 C.F.R. §§ 1.16-1.17 to Deposit Account No. 19-0741. Missing or erroneously-transmitted fees are likewise authorized to be charged to the Deposit Account. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to the Deposit Account.

Respectfully submitted,

Date October 18, 2011

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